Appendix G: Participant Safeguards

a. State Critical Event or Incident Reporting Requirements. Specify the types of critical events or incidents (including alleged abuse, neglect and exploitation) that the State requires to be reported for review and follow-up action by an appropriate authority, the individuals and/or entities that are required to report such events and incidents, and the timelines for reporting. State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

RI Law (*40.1-27-2 Duty to Report*), MHRH Licensing regulations (*DD 15 Reporting Requirements*) and the "*Requirements for Reporting Serious Incidents Involving Adults with Developmental Disabilities"* policy document developed by the Office of Quality Assurance (QA), Division of Developmental Disabilities (DDD), MHRH, specifies the types of incident classifications that must be reported to the Office of QA, DDD.

Any individual who has knowledge of or reasonable cause to know or suspect that a serious incident has or may take place must report that information to the Office of QA/DDD within 24 hours or at the end of the next business day. The Incident Management Office in QA is staffed Monday through Friday from 8:30 am to 4:00 pm to directly respond to each incident reported. There is a 24 hour telephone number to call and access to a 24 hour pager in QA for emergency situations that occur after normal work hours that may need to be immediately addressed.
The types of incidents that must be reported to the Office of QA, DDD include the following:

- Physical Abuse
- Sexual Abuse
- Sexual Exploitation
- Psychological/Verbal Abuse
- Theft/Financial Exploitation
- Neglect
- Mistreatment
- Unapproved Behavioral Intervention
- Aversive Procedures
- Serious Injury
- Hospitalization
- Serious Medication error
- Communicable Disease
- Suicide
- Death
- Missing Person
- Human Rights Violation
- Involvement of Law Enforcement
- Confidentiality Violation

b. Participant Training and Education. Describe how training and/or information is provided to participants (and/or families or legal representatives, as appropriate) concerning protections from abuse, neglect, and exploitation, including how participants (and/or families or legal representatives,

as appropriate) can notify appropriate authorities or entities when the participant may have experienced abuse, neglect or exploitation.

RI has a strong statewide advocacy organization, *Advocates in Action*, that has been providing educational programs and information directly to people with disabilities and self-advocacy groups for many years. Numerous materials have been developed in this area along with various videotapes. Advocates in Action has demonstrated leadership and initiative in sponsoring Partners in Policymaking programs, annual conferences and various workshops to assist people to learn more about their human rights, to live safely in local communities and to have a good quality of life.

People with disabilities assist staff from the Office of Quality Assurance, DDD, conduct various training programs for individuals with developmental disabilities at community agencies on understanding their human rights and protection from abuse. A booklet on *Human Rights* was developed in 2003 by people with disabilities to disseminate as part of this training. In addition a magnet with various important telephone numbers from the Division including the Office of QA along with a Liberty pin "*You Have Rights*!" is distributed to each participant in the training. Training is provided to any agency or organization that requests assistance in this area. Using people with disabilities as part of the training has been very beneficial to agencies and the training has been well received by participants attending the training.

The Office of QA has a brochure *"Abuse and Serious Incidents Must Be Reported"* and a flyer *"Report Abuse*" that has been extensively disseminated with community agencies and to some family members. Additional work is being planned to determine more specific strategies to provide this information to family members statewide.

PAL, a statewide family advocacy organization, along with the RI Developmental Disabilities Council, the RI Arc and the RI Disability Law Center have provided assistance and information to families about their rights and protections from abuse involving their family member through newsletters, training programs and technical assistance.

MHRH Licensing Regulations (DD 13 Staff Training) require that all staff from licensed community agencies be trained in the following areas:

- *Human Rights and the Roles/Responsibilities of the Office of QA/DDD*
- *Detection and Prevention of Abuse, Neglect, Mistreatment and Other Serious Human Rights Violations*
- *Procedures for Reporting Allegations of Abuse or other Human Rights Violations to the Office of Quality Assurance, DDD*
- *Teaching Strategies to Assist people to Learn the Specific Skills they Need*

The licensing regulations (*DD 7 Human Rights*) stipulate that agencies are responsible for determining the most appropriate strategy for informing people with developmental disabilities of their human rights and ensuring that people understand their human rights. Each person is at a minimum informed of his/her rights at their annual planning meeting and signs a *Statement of Human Rights* that is typically included in the person's individual record. Many agencies have developed very creative materials in this area including booklets with graphics and photos, videotapes and materials developed specifically for individuals who are deaf.

Human Rights Committees (HRC) also have responsibility for ensuring people with disabilities

and their families are educated about their rights and understand the role/responsibilities of the HRC to assist them with grievances and to have input in the agencies policies to prevent abuse and promote human rights.

c. Responsibility for Review of and Response to Critical Events or Incidents. Specify the entity (or entities) that receives reports of critical events or incidents specified in item G-1-a, the methods that are employed to evaluate such reports, and the processes and time-frames for responding to critical events or incidents, including conducting investigations.

Each reported incident is documented on the Office of Quality Assurance's *Confidential Incident Report Form* and entered weekly into the Division of developmental Disabilities' computerized Incident Tracking System. RI Law and MHRH Licensing regulations require that information on serious reportable incidents must be shared with the Office of the Attorney General and the chairperson of the agency's Human Rights Committee which is typically done within 24 hours.

All reported incidents are reviewed and discussed at a bi-weekly DDD Incident Management Committee that includes a multidisciplinary team of professional staff from the Office of Quality Assurance, Office of Health Care, and Social Services, DDD. The purpose of the Incident Management Committee is to review all incidents, which have been reported to classify each one based on the information reported, identify any further information necessary, to ensure that each incident has been responded to appropriately and to identify trends for quality improvement across the delivery service system. The committee is responsible for determining whether there is sufficient information available to classify the incident, what additional information may be necessary to obtain from the reporter or provider agency, and whether any formal action/assignment is required such as submission of further information, completion of a specific form or a formal QA Review or Investigation. Any request for additional information is documented on the *"Incident Review Follow Up Form*" and tracked on a computerized data base maintained by the Office of QA.

Staff from the Office of Quality Assurance, DDD, are trained to conduct or coordinate investigations. Specific individuals from licensed community agencies are trained and authorized to conduct investigations. Approximately 400 individuals have participated in formal investigations trainings sponsored by the Office of QA. Investigations are typically assigned to a trained individual within 24 hours of the incident being reported. The Office of QA typically investigates serious incidents of abuse and assigns trained investigators from community agencies to investigate other types of incidents. If a community agency has been authorized by QA to conduct the investigation then a staff person from QA will be assigned to coordinate the investigation to provide technical assistance and guidance to the agency investigator throughout the investigation process. All investigations are conducted utilizing a standardized process and format for the final investigation report. RI Law requires investigations to be completed within 15 working days, however, this timeframe is difficult to meet in most situations. Generally, investigations are completed within 4-8 weeks. Agencies are required to submit a *Quality Improvement Plan* within 15 working days for any investigation in which the allegation has been substantiated or inconclusive.

Information on each reported incident is also immediately shared with the Office of Office of Facilities, Program Standards and Licensure, MHRH, for any follow up action as determined necessary. Copies of all reported incidents are shared with the department's Investigation Panel which is responsible for reviewing and tracking all serious reported incidents.

All deaths are immediately reported to the Office of Health Care, DDD, by staff from QA along with a copy of the completed incident report. All deaths are reviewed by the Division's Mortality Review Committee which is responsible for identifying issues, concerns and trends; requesting more information regarding a death on the *Mortality Reporting and Review Form*; reviewing information provided by the agency; and specifying recommendations, as necessary. The Committee is chaired by the Administrator of the Office of Health Care and includes administrative staff from the Office of Quality Assurance, Social Services, Community Support, Office of Health Care and the medical director, DDD. Staff from the Office of Health Care are responsible for reviewing the completed *Mortality Forms* and requesting additional information as necessary, maintaining a database and developing a report of findings and recommendations to the Committee. Staff also provide technical assistance to the Office of QA for deaths which are formally being investigated by reviewing and assessing information provided relating to the individual.

d. Responsibility for Oversight of Critical Incidents and Events. Identify the State agency (or agencies) responsible for overseeing the reporting of and response to critical incidents or events that affect waiver participants, how this oversight is conducted, and how frequently.

The Office of Quality Assurance, DDD, is the designated office responsible for overseeing the reporting of and response to serious reportable incidents involving adults with developmental disabilities. The Office of QA is within the Division of Developmental Disabilities which is one of the programmatic divisions in the state Department of Mental Health, Retardation and Hospitals (MHRH).

Formal investigations that are conducted for serious reportable incidents result in a confidential written Investigative Analysis report which is shared with the Office of the Attorney General, as necessary and an Investigative Analysis Findings report which is shared with the agency Executive Director, Board President and Chairperson of the Human Rights Committee. A cover letter signed by the administrators of the Office of QA, DDD, and the Office of Facilities, Program Standards and Licensure, MHRH, is sent to the agency with the report with a requirement for completion of a written *Quality Improvement Plan* within 15 working days and notification of possible licensing action, as necessary.

Information on each reported incident is immediately shared by the Office of QA with the Office of Facilities, Program Standards and Licensure, MHRH, for any licensing action or follow-up, as necessary. The Office of Facilities, Program Standards and Licensure, MHRH, has taken licensing action with some agencies as a follow-up to serious incidents reported to QA and completed investigations.

An *Incident Management Trends Analysis Committee* provides a broader perspective on reported incidents and initiates more proactive response to incidents. The Committee meets quarterly and reviews data from aggregate reports relating to reported incidents. Members of the committee include staff from the Office of Quality Assurance, Office of Health Care, Office of Community Support (Social Services) and the Office of Information Technology in the Division of Developmental Disabilities as well as staff from the Office of Facilities, Program Standards and Licensure and the Office of the Director, MHRH. The committee is chaired by a staff person from the Office of Quality Assurance, DDD. The

meetings focus on trends seen across the DDD service delivery system as well as those indicated by the individual agencies. In 2004 participation on the committee was expanded to include representatives from various provider agencies, the Developmental Disabilities Council, the Disability Law Center and the RI Arc in an effort to obtain more diversified perspectives and to share information publicly relating to aggregate data on serious reportable incidents and system trends. The committee is responsible for reviewing prepared reports by the Office of Quality Assurance and Information Technology on all types of incidents reported to QA, to identify system trends, to make recommendations which could have an impact on reducing and/or preventing incidents from occurring in the future and for system improvement and to advise the Executive Director on any major issues or concerns.

The Division designed an *Agency Review* protocol in 2001 for monitoring/valuating the effectives of services provided by community agencies. The tool designed was modeled after the CMS protocol and includes the following areas:

- *Individual Record Review-Program Areas*
- *Individual Record Review-Health Care*
- *Provider Qualifications*
- *Incident Management*
- *Fiscal Review*

The process for an Agency Review involves a multi disciplinary team of staff from the DDD who participate in the Agency Review that typically takes 1-3 days. Each team member is responsible for reviewing various components of programs/services and for writing a section of the Final Report that is formally sent to the agency. The Incident Management component of the Review includes a review of the policies/procedures of the agency in the areas of incident reporting, incident management, investigations and staff training; a random review of internally reported incidents and serious reportable incidents to the Office of QA; review of follow-up action by the agency for incidents in which the allegation has been substantiated or inconclusive; and review of the agency's incident management process and Incident Management Committee minutes, documentation of any recommendations of the Incident Management Committee and documentation of follow through on the recommendations.

The agency is expected to respond to the Final Report within twenty working days with a written response to each recommendation including action to be taken, staff responsible and timeframes for completion.

Appendix G-2: Safeguards Concerning Restraints and Restrictive Interventions

This Appendix must be completed when the use of restraints and/or restrictive interventions is permitted during the course of the provision of waiver services regardless of setting. When a state prohibits the use of restraints and/or restrictive interventions during the provision of waiver services, this Appendix does not need to be completed.

a. Applicability. *Select one:*

○	This Appendix is not applicable. The State does not permit or prohibits the use of restraints or restrictive interventions *(do not complete the remaining items)*	
x	This Appendix applies. Check each that applies:	
	x	The use of personal restraints, drugs used as restraints, mechanical restraints and/or seclusion is permitted subject to State safeguards concerning their use. *Complete item G-2-b.*
	x	Services furnished to waiver participants may include the use of restrictive interventions subject to State safeguards concerning their use. *Complete items G-2-c.*

b. Safeguards Concerning Use of Restraints or Seclusion

i. Safeguards Concerning the Use of Restraints or Seclusion. Specify the safeguards that the State has established concerning the use of each type of restraint (i.e., personal restraints, drugs used as restraints, mechanical restraints or seclusion). State laws, regulations, and policies that are referenced are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

Agencies are required to specify any and all restraints used in their Behavior Management Policy and Procedure Manual, which is submitted to the state for approval. The Agency is required to review the manual annually and submit any changes to the state for approval. They are also required to specify the manner in which staff will be trained, the curriculum that will be followed and the credentials of the trainer. Physical restraint is to be used only with graduated guidance and the least level of force necessary to keep the individual safe. It may only be employed as a last resort in situations of imminent danger to the individual and/or other people. Mechanical Restraint may only be employed for individuals with whom physical restraint is not safe. Both procedures require the approval of the Agency Director, Physician, Human Rights Committee, and Professional Review Committee (an external body of 3 clinicians approved by the state and determined to have no allegiance to the agency or other conflict of interest). Plans that contain these procedures are scrutinized by the Professional Review Committee, and every attempt is made to decrease restrictiveness, utilize positive approaches, and determine the cause of the dangerous behavior in order to teach the individual new skills and replacement behaviors. **Seclusion is prohibited by Law RIGL 40.1-26-3.** Medication used for restraint is required to be prescribed by a Licensed Healthcare Provider. The Department of MHRH's Health and Wellness Standards also require that "All medication and treatment orders be reviewed and renewed annually and as otherwise indicated by the licensed Healthcare Provider."

ii. State Oversight Responsibility. Specify the State agency (or agencies) responsible for overseeing the use of restraints or seclusion and ensuring that State safeguards concerning their use are followed and how such oversight is conducted and its frequency:

The Department of MHRH Division of Developmental Disabilities (MHRH/DDD) Office of Community Support is responsible for overseeing the use of restraint. Seclusion is prohibited by law, RIGL 40-1-26-3. Oversight is accomplished through the requirement that every individual with a behavior intervention plan containing a restraint procedure be reviewed and approved at least annually by a Professional Review Committtee (PRC). The PRC has the discretion to require more frequent review in any case where there is cause for concern. Procedures may NOT be employed without PRC approval, and if a plan does not meet PRC approval, MHRH/ DDD is notified and intervenes until safe and effective resolution is reached. Any unauthorized use of restraint is reported to the DDD Office of Quality Assurance, and is investigated. Agencies submit a **Quarterly Report of Restrictive Procedures** to the DDD Office of Community Support, as well as an Agency **Annual Restraint Report.**

c. Safeguards Concerning the Use of Restrictive Interventions

i. Safeguards Concerning the Use of Restrictive Interventions. Specify the safeguards that the State has in effect concerning the use of interventions that restrict participant movement, participant access to other individuals, locations or activities, restrict participant rights or employ aversive methods (not including restraints or seclusion) to modify behavior. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency.

The MHRH Licensing Regulations (Sections DDBI 21-26) are highly prescriptive with the level of justification and scrutiny required in cases where restrictive procedures must be employed due to the dangerousness or severity of a given pattern of behavior(s). Chapter 26, 40.1 of RI General Law prohibits many aversive interventions, and in conjunction with the above referenced regulations, specifies many conditions, analysis', timeframes, training, data, multiple authorizing signatures and external review and approval of both a Professional Review Committee (PRC), and Human Rights Committee (HRC).

ii. State Oversight Responsibility. Specify the State agency (or agencies) responsible for monitoring and overseeing the use of restrictive interventions and how this oversight is conducted and its frequency:

The Department of MHRH/DDD Office of Community Support is responsible for this function. This is done in conjunction with the independent Professional Review Committees (PRCs) described above. Quarterly reports evidencing the PRC review and approval status of every specifically described restrictive intervention are provided by the agencies to the DDD Office of Community Support.

Appendix G-3: Medication Management and Administration

This Appendix must be completed when waiver services are furnished to participants who are served in licensed or unlicensed living arrangements where a provider has round-the-clock responsibility for the health and welfare of residents. The Appendix does not need to be completed when waiver participants are served exclusively in their own personal residences or in the home of a family member.

a. Applicability. Select one:

x	**Yes**. This Appendix applies *(complete the remaining items)*.
○	**No**. This Appendix is t applicable *(do not complete the remaining items)*.

b. Medication Management and Follow-Up

i. Responsibility. Specify the entity (or entities) that have ongoing responsibility for monitoring participant medication regimens, the methods for conducting monitoring, and the frequency of monitoring.

The Office of Quality Assurance within the Department of Mental Health, Retardation and Hospitals' (MHRH) Division of Developmental Disabilities (DDD) has the responsibility to investigate or cause to be investigated all serious medication errors.

The Division of Developmental Disabilities' Incident Management Committee meets twice each week to review all incidents that have been called in to the Office of Quality Assurance. The Incident Management Committee includes staff from the Office of Quality assurance, Office of Health Care and Social Services, DDD.

ii. Methods of State Oversight and Follow-Up. Describe: (a) the method(s) that the State uses to ensure that participant medications are managed appropriately, including: (a) the identification of potentially harmful practices (e.g., the concurrent use of contraindicated medications); (b) the method(s) for following up on potentially harmful practices; and, (c) the State agency (or agencies) that is responsible for follow-up and oversight.

The MHRH Licensing Regulations require that licensed developmental disabilities provider agencies report serious incidents. The definition of "serious incidents" in the MHRH Licensing regulations and in the DDD/Quality Assurance Reporting Requirements includes Medication Errors. A reportable medication error is defined as "the administration of a medication or treatment other than as prescribed, or the failure to administer a prescribed medication or treatment, resulting in the need for assessment/treatment in an emergency room, treatment center, physician's office, or admission to a hospital. A reportable medication error also includes a series of repeated errors or a pattern of errors."

The MHRH Licensing Regulations require provider agencies to "complete and maintain written incident reports documenting any abuse, neglect, mistreatment, violation of a person's human rights, or other serious incident. Licensed developmental disabilities provider agencies are required to have an Internal Incident Review Committee that meets at minimum on a quarterly basis to review all incidents reported to DDD Quality Assurance.

The *Health and Wellness Standards* section of the MHRH Licensing Regulations requires that "If medication errors or omissions occur, the nature of the error or reason for the omission shall be documented according to the agency's written policy and procedure". The *Health and Wellness Standards* also require that "all medication and treatment orders shall be reviewed and renewed annually, and as otherwise indicated by the licensed health care provider".

c. Medication Administration by Waiver Providers

i. Provider Administration of Medications. *Select one*:

X	Waiver providers are responsible for the administration of medications to waiver participants who cannot self-administer and/or have responsibility to oversee participant self-administration of medications. *(complete the remaining items)*
○	Not applicable (*do not complete the remaining items*)

ii. State Policy. Summarize the State policies that apply to the administration of medications by waiver providers or waiver provider responsibilities when participants self-administer medications, including (if applicable) policies concerning medication administration by non-medical waiver provider personnel. State laws, regulations, and policies referenced in the specification are available to CMS upon request through the Medicaid agency or the operating agency (if applicable).

The *Health and Wellness Standards* section of the Department of Mental Health, Retardation and Hospitals' (MHRH) Licensing Regulations describes the requirements for training and competency assessment for Direct Support Staff (unlicensed personnel) administering medications. Additionally, the *Health and Wellness Standards* require licensed developmental disabilities provider agencies to have a written policy and procedure describing medication safeguards and support protocols for individuals who self-administer their medications.

iii. Medication Error Reporting. *Select one of the following:*

X	Providers that are responsible for medication administration are required to *both* record and report medication errors to a State agency (or agencies). *Complete the following three items:*
	(a) Specify State agency (or agencies) to which errors are reported:
	The Department of Mental Health, Retardation and Hospitals' Division of Developmental Disabilities/Office of Quality Assurance.
	(b) Specify the types of medication errors that providers are required to *record:*
	Medication errors as defined in Section b (ii).
	(c) Specify the types of medication errors that providers must *report* to the State:
	Medication errors as defined in Section (b) ii.
○	Providers responsible for medication administration are required to *record* medication errors but make information about medication errors available only when requested by the State. Specify the types of medication errors that providers are required to record:

iv. State Oversight Responsibility. Specify the State agency (or agencies) responsible for monitoring the performance of waiver providers in the administration of medications to waiver participants and how monitoring is performed and its frequency.

The medication administration requirements described within the *Health and Wellness Standards* will be monitored during the course of provider agency licensing surveys conducted by the Department.